UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,640	08/10/2000	QUANG TRI NGUYEN	045636-5033	1376

9629 7590 09/21/2005

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,640	NGUYEN ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-21 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *17-21 and 28-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16,24-27 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

GT

Detailed Office Action

Status of the Claims

Claims 1-14, 16-21, and 24-38 are pending in the instant application. Applicants' election with traverse (only as it pertains to Groups I, II, and VII) of Group I (claims 1-10) in the response dated 04 April, 2005, is acknowledged. Applicants requested further examination of Groups II and VII along with Group I. Applicants note that claims 37 and 38 are directed toward a diagnostic nucleic acids which should be included in Group I. The examiner concurs with this assessment. It was further suggested that the kit of claim 36 should also be included in Group I. The examiner does not concur with this assessment. Applicants are reminded that a kit contains additional materials (i.e., packaging, inserts, instructions) that do not share any special technical features with the claimed invention and will necessitate further consideration and searching. Accordingly, the restriction requirement should read as follows:

a. Group I, claims 1-10, 37, and 38, drawn to sundry **erythroviral nucleic acids, probes, primers, and complementary sequences thereof**.

b. Group II, claims 11-14, 16, and 24-27, drawn to various diagnostic, screening, and typing methods employing sundry **nucleic acids, probes, primers, and complementary sequences thereof**.

c. Group III, claims 17-20, 28, and 29, drawn to sundry **proteins or polypeptide fragments thereof** and immunogenic compositions containing said proteins or fragments.

d. Group IV, claims 21, 30, and 31, drawn to **antibodies** directed against sundry erythroviral proteins, polypeptides, or fragments thereof.

e. Group V, claims 32 and 33, drawn to ***in vitro* screening methods** employing sundry erythroviral **proteins, polypeptides, or fragments thereof.**

f. Group VI, claims 34 and 35, drawn to ***in vitro* screening methodologies** employing sundry erythroviral-specific **antibodies**.

g. Group VII, claim 36, drawn to a **diagnostic kit** comprising sundry **nucleic acids, probes, primers, and complementary sequences thereof**.

h. Group VIII, claim 36, drawn to a **diagnostic kit** comprising sundry **proteins** or **polypeptide fragments** thereof.

i. Group IX, claim 36, drawn to a **diagnostic kit** comprising **antibodies** directed against sundry erythroviral proteins, polypeptides, or fragments thereof.

Pursuant to unity of invention practice as set forth under 37 C.F.R. § 1.141, 1.475, and 1.499, the examiner agrees with applicants' request that Groups I, II, and VII be rejoined. Accordingly, claims 1-14, 16, 24-27, and 36-38 are currently under examination. Claims 17-21 and 24-35 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.72(b)

The abstract of the disclosure is objected to because it fails to comply with 37 C.F.R. § 1.72(b). It is noted that an abstract has been supplied from the PCT/FR98/02615 application which is inappropriate. Applicants are reminded that all application papers (specification, including claims, abstract, any drawings, oath or declaration, and other papers), and also papers subsequently filed, must have each page plainly written on only one side of a sheet of paper. The specification must commence on a separate sheet. **Each sheet including part of the specification may not include other parts of the application or other information.** The claim(s), abstract and sequence listing (if any) should not be included on a

sheet including any other part of the application (37 C.F.R. § 1.71(f)). The claim or claims must commence on a separate sheet or electronic page and any sheet including a claim or portion of a claim may not contain any other parts of the application or other material (37 C.F.R. § 1.75(h)). **The abstract must commence on a separate sheet and any sheet including an abstract or portion of an abstract may not contain any other parts of the application or other material (37 C.F.R. § 1.72(b)).** See M.P.E.P. § 608.01. Applicants are required to provide a replacement abstract on a separate sheet that does not contain additional material.

Claim Objections

Claim 36 is objected to because it fails to reflect the restriction/election requirement. Applicants are reminded that the elected claims are directed toward a diagnostic kit comprising nucleic acids, **not** polypeptides or antibodies. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

Claims 1-14, 16, 24-27, and 36-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claims 1, 7, and 36 references "**stringent**" hybridization conditions which is vague and indefinite because it is a relative term and fails to provide any meaningful guidance pertaining to the actual parameters encompassed by the claim language. The hybridization parameters can vary considerably, even under

"standard conditions" (Wahl *et al.*, 1987; Wallace and Miyada, 1987). A number of parameters govern the stringency of the hybridization including the **length of the polynucleotide probe, hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration**, and **salt concentration**. Changes in these parameters will affect the specificity of any given probe. Thus, in order to ascertain the metes and bounds of the patent protection desired, the skilled artisan would require a knowledge of these parameters. Appropriate amendment of the claim language, as supported by the disclosure, is required.

Claims 1, 7, and 8 also contain a reference to V9 variants that cannot be recognized "**molecularly**" as B19 because of the genetic divergence between them which is confusing. Both V9 and B19 are genetically related because they are both erythroviruses. Accordingly, they share common structural genes and nucleotide sequences. Portions (i.e., restriction fragments) of the B19 genome will recognize corresponding regions of the V9 genome. Thus, this recitation is confusing. It is suggested that applicants amend the claim language to recite "**an erythrovirus V9 variant, wherein said variant displays less than or equal to 6% genetic relatedness as compared to the prototypical V9 isolate consisting of SEQ ID NO.: 1 and greater than or equal to 10% genetic relatedness as compared to the prototypical B19 isolate**" or something similar thereto as supported by the disclosure.

Claim 1 also references "**genomic sequences**" which is vague and indefinite because it is not readily manifest if the claims are directed toward full-length erythroviral genomic sequences or sub-genomic/fragments of the full-length viral genome. Appropriate correction is required.

Claims 3-7, 10, 11, 13, 14, and 36 are vague and indefinite because it is not readily manifest if the claim language is "open" or "closed". The claims simply recite SEQ ID NOS.: without

providing any further limitations pertaining to whether or not the claim language encompasses larger fragments **comprising** these sequences or whether the claims are directed specifically (**consisting**) at these sequences. Appropriate amendment of the claim language is required. For the purposes of examination, the examiner is treating the claim language as "open".

Claim 10 is vague and indefinite for referencing a diagnostic reagent that allows for "**differential detection of type V9 erythroviruses**". The specificity of this reagent is not readily manifest. For instance, is the reagent specific for just V9 isolates under a wide variety of assay conditions or can it also detect other erythrovirus isolates? Appropriate clarification and correction are required.

Claims 11 and 14 are vague and indefinite for referencing the "**differential diagnosis**" of an erythrovirus. The term "**differential diagnosis**" has an art-recognized meaning and refers to the determination of which one of two or more **diseases** or **conditions** a patient is suffering from, by systematically comparing and contrasting their **clinical findings**. Claim 11 does not accomplish this task but rather simply detects V9 or related erythroviruses. Appropriate correction is required.

Claim 11 is also incomplete for omitting essential positive methods steps, such omission amounting to a gap between the steps. The claim purportedly "**differentially diagnoses**" erythroviruses yet the claim steps fail to perform such a function. The claims fail to set forth any of the salient steps and reaction conditions required to perform any sort of comparative analysis. The claims simply provide a single poorly defined contacting step involving a sample and V9 probe and a poorly defined detection step. However, the steps as currently claimed, fail to accomplish the stated objective.

Claim 16 is directed toward a method of screening and typing

erythrovirus V9 or a related virus by simply contacting the viral nucleic acid with a V9 probe. The claim is incomplete for omitting essential positive methods steps, such omission amounting to a gap between the steps. In order to type a virus, the skilled artisan generally uses a panel of probes pertaining to different viral isolates (e.g., A, B, C, D, E, and F) and sub-isolates (e.g., A_1, A_2, A_3, A_4, etc.) to test the sample of interest under stringent hybridization conditions. This allows the skilled artisan to actually ascertain if any given isolate/type is present in the sample. Claim 16 fails to perform this function. The claims fails to include all the salient assay steps and reagents that are required for a "typing" reaction. Appropriate correction is required.

Claim 24 is vague and indefinite for referencing "**screening diagnosis of infection**". It is not readily manifest what this term encompasses. It is suggested applicants amend the claim language to recite "a method for the detection of an erythrovirus in an individual ..." The claim is also incomplete for omitting essential positive methods steps, such omission amounting to a gap between the steps. The claim fails to include the salient assay steps and reagents that allow the skilled artisan to perform the stated objective. The claim simply recites a detection step without providing any of the salient characteristics and features. The claim fails to recite a sample preparative step, hybridization reaction and conditions, washing step, and suitable detection step. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set

forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *University of Rochester* v. *G. D. Searle & Co., Inc.*,, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of "**variant erythroviruses**". An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method

of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a Alaundry list≅ disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written

description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The claims of the instant application are broadly directed toward variant erythroviruses. The disclosure describes the isolation and molecular characterization of a **single** novel erythrovirus termed V9. The full-length genomic nucleotide sequence (5028 nt) is set forth in SEQ ID NO.:1. This virus displays more than 10% genetic divergence as compared to the prototypical erythroviral isolate B19. Oligonucleotide probes and primers prepared from this sequence were also disclosed. However, the specification does **not** provide any structural or functional information pertaining to any other "variant" erythroviruses. The specification does not disclose the cloning and sequencing of any other viral isolates. The specification does not provide any significant defining criteria for other V9 isolates. The disclosure also fails to identify those portions of the viral genome that can tolerate nucleotide sequence additions, deletions, or substitutions and still retain all the characteristics of a V9 variant. Thus, the skilled artisan would reasonably conclude that applicants were in possession of the viral isolate V9 set forth in SEQ ID NO.: 1, as well as, oligonucleotide probes and primers derived from this sequence. However, the skilled artisan would also reasonably conclude that applicants were not in possession of any other V9 variants and could not readily envisage the structure

of said variants.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648
09/10/2005